

# Exhibit H

# Guidelines for the Ethical Use of Neuroimages in Medical Testimony: Report of a Multidisciplinary Consensus Conference

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## ABSTRACT

**SUMMARY:** With rapid advances in neuroimaging technology, there is growing concern over potential misuse of neuroradiologic imaging data in legal matters. On December 7 and 8, 2012, a multidisciplinary consensus conference, *Use and Abuse of Neuroimaging in the Courtroom*, was held at Emory University in Atlanta, Georgia. Through this interactive forum, a highly select group of experts—including neuroradiologists, neurologists, forensic psychiatrists, neuropsychologists, neuroscientists, legal scholars, imaging statisticians, judges, practicing attorneys, and neuroethicists—discussed the complex issues involved in the use of neuroimaging data entered into legal evidence and for associated expert testimony. The specific contexts of criminal cases, child abuse, and head trauma were especially considered. The purpose of the conference was to inform the development of guidelines on expert testimony for the American Society of Neuroradiology and to provide principles for courts on the ethical use of neuroimaging data as evidence. This report summarizes the conference and resulting recommendations.

**ABBREVIATIONS:** AMA = American Medical Association; ASNR = American Society of Neuroradiology

Neuroradiologic imaging techniques have rapidly evolved during the past 3 decades to offer exquisite anatomic detail and, increasingly, a variety of functional insights. While excellent for diagnosing neurologic disease, current neuroimaging technologies have a limited role in the clinical setting of behavioral disorders or psychiatric disease. Research using brain imaging spans a wide range of ongoing investigations into the neurobiologic mechanisms underlying normal human behavior and psychiatric disorders. Promising approaches for diagnostic and/or prognostic imaging for cognitive impairment (including following mild traumatic brain injury),<sup>1</sup> lie detection,<sup>2,3</sup> psychoses,<sup>4,5</sup> mood dis-

orders,<sup>6</sup> and other behavioral paradigms<sup>7</sup> are evolving. Much of this research is performed with study designs that compare groups of well-characterized subjects, but validation in single-subject analyses is often lacking.<sup>8</sup> With advancements in brain imaging and postprocessing techniques, both acquisition methods and data interpretation can vary greatly by site and scanner.<sup>9</sup> This variation makes the standardization of image generation highly challenging.

While medical images are commonly included in courtroom evidence, neuroimaging presents special complexity, and both structural and functional neuroimaging remains controversial in several common forensic settings. The specific use of functional imaging for making inferences about human behavior or motivation is particularly problematic.<sup>10</sup> Technologies that promise “images of” or “windows to” the mind are especially compelling and enticing to general audiences. Indeed studies have suggested that nonsensical science texts are more convincing when accompanied by brain-based data and especially a brain image.<sup>11,12</sup> Despite these concerns, however, there is no comprehensive set of guidelines to inform imaging experts or the courts. In 1996, the Brain Imaging Council of the Society of Nuclear Medicine published a cautionary note warning of the potential for over-reach with positron-emission tomography and single-photon emission tomography of the brain in expert testimony.<sup>13</sup> Yet, although general guidelines for physicians engaged in medical testimony for radiology<sup>14,15</sup> and other medical specialties<sup>16,17</sup> do exist, there is

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American Society for Functional Neuroradiology DTI Guidelines Disclaimer: Please note that DTI and tractography are based on certain biophysical assumptions and mathematical approximations; their results should be interpreted in conjunction with conventional anatomical imaging as well as other clinical data including physical examination and, if clinically indicated, intraoperative subcortical stimulation.<sup>46</sup>

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an unmet need to address specific guidelines on expert testimony concerning the unique challenges of brain imaging.

A consensus conference, supported by the American Society of Neuroradiology (ASNR), the Atlanta Clinical and Translational Science Institute, and the Emory University Neuroscience Initiative, brought together experts from multiple disciplines—including neuroradiology, ethics, law, biostatistics, forensic psychiatry, neuroscience, neurology, and neuropsychology—to inform the development of guidelines on the ethical use of neuroimaging in the courtroom. We considered 5 framing questions:

- 1) What standards or guidelines should be used in testimony about brain-behavior relationships to determine when generalized research findings are applicable to individuals?
- 2) What kinds of testimony are outside an expert's expertise/qualifications?
- 3) How can bias in medical testimony be diminished?
- 4) How do judicial standards of legal evidence apply to medical expert opinions on causality and associations in court?
- 5) When is medical testimony outside what is generally accepted in the field and is such testimony ever justifiable?

On the basis of several case examples considered within the framework of the 5 framing questions, we discussed the need for guidelines and considered the following key issues.

### **Need for Guidelines**

The obligation to protect the public trust by ensuring that expert testimony is accurate and reliable is well recognized.<sup>18</sup> Yet, despite concern over insufficient regulation of the use of neuroimaging in forensic evidence,<sup>19</sup> some professional societies have been reluctant to sanction members for medical testimony, deemed to be inappropriate due to concerns about impugning the individual's reputation.<sup>15</sup> In *Austin v American Association of Neurologic Surgeons*,<sup>20</sup> the courts upheld the right of professional societies to sanction members for irresponsible expert testimony. The position of the American Medical Association (AMA) is that expert witness testimony can be considered the practice of medicine and thus is subject to peer review (<http://www.ama-assn.org/resources/doc/code-medical-ethics/907a.pdf>) (AMA H-265-993). In fact, the Ethics Committee of the American College of Radiology has reviewed medical testimony and sanctioned members.<sup>21</sup> Because expert witnesses are secured to assist triers of fact in achieving truth, a need for guidelines that qualify the admissibility and reliability of proffered neuroimaging evidence is self-evident. The material that follows highlights themes and topical areas that were especially prominent as the guideline discussion proceeded at the consensus conference.

### **Key Considerations**

**Qualifications of Experts and Scope of Testimony.** If expert medical testimony is to be valued, it must be balanced, accurate, and aligned with the qualifications of the witness. If indeed expert medical testimony represents the practice of medicine, as postulated by the AMA (AMA H-265-993), then it should be subject to peer review.

While it is generally agreed that expert testimony should be provided only by those who have considerable experience in the relevant subject matter,<sup>22</sup> most professional society guidelines do

not clearly address testimony that is outside of subspecialty expertise. Is a specialist's testimony superior to that of a generalist? One would assume that expert testimony should be given by an expert, yet the AMA report states that an expert witness should have education, training, and occupational experience comparable with those of the defendant in medical malpractice cases. This approach applies primarily to experts who are reviewing cases for adherence to the standard of care, in which physicians of comparable knowledge and experience may be optimal choices. In cases in which causation is an issue or advanced techniques are involved, then greater expertise may be desirable to more accurately delineate the findings and relevant differential diagnosis. For example, in birth injury cases, a wide range of diagnoses (eg, hypoxic-ischemic injury, congenital malformation, in utero infection, complex inborn error of metabolism, and so forth) may be consistent with the imaging presentation.

Several society guidelines require that the expert providing medical testimony be board-certified in the relevant field.<sup>16,23</sup> However, nonphysician, nonradiologist professionals who are expert in advanced brain imaging techniques in research settings have been called to testify on the diagnostic and prognostic value of imaging studies. In such cases, jurors may assume causality from testimony on brain imaging even though clinical context is absent. The distinction between medical and scientific testimony is not always clear to the lay person.

**Bias in Expert Testimony.** There are several sources of bias that may account for substantial variability in expert testimony, even for the most well-meaning professionals.<sup>24</sup> Hindsight bias is a widely recognized phenomenon: Faced with the knowledge of an abnormality, radiologists are more likely to detect a lesion on imaging.<sup>25</sup> Outcome bias also comes into play in the retrospective nature of reviewing imaging studies for medical testimony, when the reader is already aware of an adverse event.<sup>25</sup> Financial incentives may be a particularly concerning source of bias.<sup>26</sup> Given the adversarial nature of legal proceedings, innate tendencies toward reciprocity may introduce subconscious bias,<sup>27,28</sup> and attorneys seek experts who are inclined to support their position. Kesselheim and Studdert<sup>29</sup> observed that physicians who testified frequently tended to act consistently for one side (ie, plaintiff or defendant). Alternatively, in cases that use functional neuroimaging methods typically performed in the research setting, the expert may be influenced by a professional investment in promoting his or her research area or specific research findings.<sup>30</sup> In some situations, such as death row cases, the expert may also be biased by a political or ethical position, such as opposition to the death penalty.

### **Scientific Validity**

Advanced brain imaging techniques, such as functional MR imaging, diffusion tensor imaging, perfusion imaging, PET, and SPECT, are used in care in only a few clinical settings in which sufficient literature and/or clinical evidence has demonstrated sensitivity and specificity. Such techniques are most often applied in the research setting, typically by using group comparisons, and statistical validity is a well-recognized challenge for fMRI. The translation of fMRI and other experimental neuroimaging methods to single-subject uses is highly challenging and, thus far, is

applied only in clinical situations in which a relatively strong activation signal may be obtained, such as in presurgical mapping of the motor cortex. The validity of using single-subject fMRI data to uncover evidence of behavioral aberration, pain, or deception is more problematic.<sup>19,31</sup> Furthermore, the applicability of normative imaging databases (typically comprising young, healthy subjects) in courtroom testimony is questionable. We also note that the use of normative imaging databases for comparisons with individual subjects for the purpose of expert witness testimony may constitute an inappropriate use of materials collected from research subjects.

The reliability of scientific evidence is judged according to 1 of 2 alternative rules, depending on the jurisdiction. The dominant standard originating from the 1993 case *Daubert v Merrell Dow Pharmaceuticals* (509 U.S. 579, 1993) assigns a duty to the trial judge to serve as a gatekeeper for scientific evidence. This case considers 5 factors: whether the expert's theory can and has been tested, whether the theory has been subject to peer review, the known or expected error rate, the existence and maintenance of standards controlling the operation of the technique, and acceptability in the relevant scientific community. The expert's opinion must be based on scientific knowledge. The broader and older ruling known as the Frye standard<sup>32</sup> remains in effect in states that have not elected to follow the *Daubert* approach. Frye requires that the party introducing the evidence show that the theory or methodology used by the expert is generally accepted within the relevant scientific community; it does not consider the reliability of the proposed evidence.<sup>10</sup>

The growth of technology development in neuroimaging is staggering, making it difficult to develop standards for its acquisition and postacquisition processing. For example, MR imaging by using DTI is a highly promising technique for evaluating the integrity of brain white matter, yet results may vary by scanner field strength, scanner type, pulse sequence, and postprocessing. The representational nature of color-coded DTI fiber-tracking maps may not be evident to the lay public, such as a jury, who may assume they are pictures of actual brain connections.<sup>33</sup> Similarly, it may not be obvious that areas of activation generated from fMRI are a statistical representation of data, while raw data are rarely peer-reviewed for acceptability of methods. Because of the strong presence and appearance of objectivity of the visual images that are the products of neuroimaging technology, some have argued that their value may be outweighed by their potential prejudicial influence.<sup>19,34</sup>

### Use and Abuse Cases

We used breakout groups to explore cases that were exemplary of use and abuse of neuroradiologic data in the courtroom. Consensus conference participants considered 4 cases regarding the use of imaging in the courtroom: 1) conventional (structural) imaging, 2) criminal/forensics, 3) brain trauma, and 4) child abuse. The use of neuroimaging in criminal trials and brain trauma may be most controversial and thus was emphasized.

### Conventional (Structural) Imaging

Because much of clinical imaging interpretation is nonquantitative, there is an imperative for experts to use standardized, ac-

cepted medical terminology in describing findings. Relevant definitions of what constitutes normal variation are highly desirable yet often lacking.<sup>35</sup> Issues bearing on the credentials and experience of the expert witness are also important to consider. Particularly in malpractice cases, peer-review panels could add validity, because the standard of care can be difficult to establish. Furthermore, the context of the imaging data should be evaluated in light of other relevant records.

### Neuroimaging in Criminal Cases

Brain imaging findings have limited application to the primary question of the court of determining criminal intent.<sup>36</sup> The practice of performing imaging studies on a defendant in order to shed light on brain function or state of mind at the time of a prior criminal act is problematic. The retrospective nature of this evaluation makes it particularly difficult to attribute causality to specific imaging findings. Currently brain imaging methods cannot readily determine whether a defendant knew right from wrong or maintained criminal intent or *mens rea* at the time of the criminal act. Also, there is an inherent difficulty in translating mechanistic (neural) system data into human behavior. While functional imaging research has correlated numerous behaviors and moods with regions of the brain, issues of individual variation, plasticity, and the challenge of assuming knowledge of past motivational states limits the utility of brain images to infer causality of behaviors. Morse<sup>37</sup> argued that the detection of structural or functional brain findings that correlate with behavioral syndromes does not convincingly imply causation or criminal responsibility, or predict future behaviors.

Neuroimaging evidence is most often introduced in criminal cases in the sentencing or punishment phase, to address the consideration of mitigating circumstances.<sup>32</sup> Criminal defense attorneys are increasingly using brain imaging data and neuroimaging experts in capital sentencing. Attorneys may argue that while the defendant may be legally guilty, evidence of abnormal brain function diminishes his or her culpability.<sup>38</sup> From a compassionate perspective, the argument that a defendant's brain may be shown to be "hard-wired" to predispose the individual to criminal behaviors is appealing. Yet this approach may be used not only to mitigate sentences (by implying a lack of criminal intent) but also to support more severe sentencing (ie, hard-wired individuals may pose a continued threat to society). Also, neuroimaging evidence for the lack of complete myelination of the adolescent brain has been used to conclude that adolescents' culpability should be inherently mitigated.<sup>39</sup> Still, there is substantial debate as to whether brain imaging can contribute value to the behavioral approach that courts have traditionally used to comprehend these issues.

### Brain Trauma

Public attention to the sequelae of brain trauma has grown.<sup>40</sup> In particular, DTI is under intense investigation for its potential application for predicting persistent cognitive deficits in individuals who have experienced trauma. Some investigations have demonstrated relationships between DTI findings and clinical symptoms and/or outcome,<sup>1,41,42</sup> though others have not.<sup>43,44</sup> This technique promises to offer unique insights into the natural history of

brain injury and potentially inform therapeutic approaches. Yet the manner in which DTI data are acquired produces findings that not only lack specificity but also continue to be highly variable across institutions and among researchers.<sup>45</sup> The American Society for Functional Neuroradiology has developed general guidelines for the acquisition and postprocessing of DTI data.<sup>46</sup> However, the rapid evolution of this technique has contributed to the challenge of achieving true standardization. At present, the American Society for Functional Neuroradiology guidelines include a suggested disclaimer in clinical reports of DTI and note that “it is critical that physicians basing clinical decisions on DTI be familiar with the limitations and potential pitfalls inherent to the technique.”<sup>43</sup>

Furthermore, the neuroradiology community has not arrived at a consensus view of the value of DTI in (particularly mild) head trauma. Nonspecific patterns or findings obtained with DTI prohibit the confirmation or diagnosis of mild TBI with reliability. If DTI or other nonspecific imaging findings are introduced into legal evidence, the expert should offer alternative explanations for the findings, including technical factors and normal variations.<sup>42</sup>

### **Child Abuse**

Shaken Baby Syndrome, with its traditional trilogy of subdural hematoma, retinal hemorrhages, and diffuse axonal injury, can cause devastating brain injury in young children and infants.<sup>48</sup> Neuroradiologic imaging coupled with a consistent clinical examination may detect a pattern of lesions consistent with Shaken Baby Syndrome and thus provide diagnostic evidence of nonaccidental trauma.<sup>49</sup> Yet the specificity of these findings is not as robust as was previously thought.<sup>50</sup> New questions and speculations in this area have been prompted by other potential medical explanations including stroke, infection, sinus thrombosis, and previous bleeding due to an undiagnosed clotting disorder.<sup>49,51</sup> Therefore, it is vital that the expert witness articulate what other diagnoses may present similarly.

Conference participants emphasized the need for balanced objectivity in presenting testimony and in including the identification of other possibilities in the differential diagnosis. Due to the special expertise required to diagnose nonaccidental trauma in children, experts should be trained in neuroradiology and include pediatric neuroradiology in their clinical practice.

### **Proposed Standards**

On the basis of the above, the following guidelines for neuroradiology imaging testimony are put forth. These may both serve to guide subspecialty societies like the ASNR and inform the legal community.

1) Experts should present all relevant facts available in their testimony, ensure truthfulness and balance, and consider opposing points of view.

2) Experts should specify known deviations from standard practice.

3) Experts should have substantive knowledge and experience in the area in which they are testifying.

4) Experts should use standard terminology and describe standardization methods and the cohort characteristic from which claims are determined, when applicable.

5) Nonvalidated findings that are used to inform clinical pathology should be approached with great caution.

6) Recognized appropriateness guidelines should be used to assess whether the imaging technique used is appropriate for the particular question.

7) Experts should avoid drawing conclusions about specific behaviors based on the imaging data alone.

8) Experts should be willing to submit their testimony for peer review.

9) Experts should be prepared to provide a description of the nature of the neuroimages (eg, representational/statistical maps when derived from computational postprocessing of several images) and how they were acquired.

10) Raw images and raw data should be made available for replication if requested.

11) Experts should be able to explain the reasoning behind their conclusions.

12) False-positive rates should be known and considered if the expert's testimony includes quantitative imaging.

13) Experts should be prepared to discuss limitations of the technology and provide both confirming research and disconfirming studies.

### **Sanction**

Leaders of professional societies may be reluctant to sanction members who act outside of established guidelines and/or offer inappropriate testimony because this may put the professional society at risk of legal action from a disgruntled member. Yet, if medical expert testimony is indeed a part of the practice of medicine, as observed by the AMA, then developing procedures for peer review of testimony and potential sanction is warranted.<sup>21</sup> In addition, while fear of sanctions might prevent experts from testifying, the AMA guidelines also suggest that serving as an expert witness when called upon is also a professional, medical responsibility.

### **CONCLUSIONS**

While neuroimaging involves powerful and robust technologies, its premature or inappropriate use in the courtroom may cause more harm than good. Premature use may not only have detrimental effects in the legal setting but may also breed societal distrust in innovative technologies that could hinder their future development and research. On the basis of a multidisciplinary consensus conference, we have developed a set of guidelines that may be used by neuroradiologists and the courts to ensure that images and expert testimony introduced into evidence are reliable. It is our intent that both appropriate medical and legal professional societies consider adoption of these guidelines to provide a standardized ethical foundation for the medical testimony involving neuroimaging.

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